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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,165	10/04/2002	Sheena M. Loosmore	1038-1217 MIS:jb	4814

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,165	LOOSMORE ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sasaki et al. 1999 (one page)*.

Lack of Unity

1) Claims 1-24 are under prosecution.

2) This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-11, drawn to a nucleic acid molecule having a *M. catarrhalis* nucleotide sequence selected from the group consisting of SEQ ID NO: 5, 6, 8 or 10, or the complementary sequence thereto; a nucleotide sequence encoding an about 200 kDa OMP as recited in part (c); SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 45, SEQ ID NO: 46, SEQ ID NO: 47, SEQ ID NO: 48 and a nucleotide sequence encoding a 5`-truncation, or a 5`-truncation and 3`-truncation of a gene encoding an about 200 kDa OMP of *M. catarrhalis;* a vector and a host cell comprising the same.

II. Claims 12-18, drawn to a recombinant outer membrane protein of *Moraxella catarrhalis* or truncation thereof, and a composition comprising the same.

III. Claims 19 and 20, drawn to a method of inducing protection against disease caused by *Moraxella catarrhalis* by administering a composition comprising outer membrane protein of *M. catarrhalis* or truncation thereof.

IV. Claims 21-24, drawn to a method for the production of a 200 kDa outer membrane protein of *M. catarrhalis* or a C-terminal half thereof by transforming a host with a vector comprising a nucleic acid molecule and growing the host cell.

3) Inventions I-IV lack unity of invention due to the absence of a special technical feature. The special technical feature of the first claimed product of invention I is a nucleic acid molecule having a *M. catarrhalis* nucleotide sequence of SEQ ID NO: 5, 6, 8 or 10, or the complementary sequence thereto, or a nucleotide sequence encoding an about 200 kDa OMP as recited in part (c) as depicted above. Such a product, however, was already disclosed in the art. For example, Sasaki *et al.* (*In*: *Abstracts of the American Society for Microbiology*, Chicago, Illinois, USA, vol. 99, page 89, abstract B/D-306, 30 May - 03 June 1999, abstract) (Sasaki *et al.*, 1999) taught a cloned or PCR-amplified gene (i.e., a nucleic acid molecule) encoding a 200 kD protein of *M. catarrhalis* which is

characterized by a G tract wherein the number of Gs present is nine (i.e., a multiple of 3) which meets the nucleic acid molecule of part (c) of claim 1. Therefore, the special technical feature of invention I does not define over the prior art. Although individually, the first claimed product and the method of making and the first method of using this product, for example of invention IV, are a permitted combination of categories under PCT Rule 13.2, since the special technical feature is already disclosed in the art, the special technical feature is not a unifying feature. Furthermore, technically, the absence of a special technical feature would permit the separation of method of using the product from the product itself.

The special technical features of inventions II-IV are delineated above. The nucleic acid molecule of invention I does not share significant common structure with the recombinant protein of invention II, the former comprising purine and pyrimidine units and the latter comprising amino acid residues. The methods of inventions IV and V do not share significant common method steps, the products/ compositions used, and the ultimate goals accomplished.

4) This application contains claims directed to more than one species to be examined. The nucleic acid molecule species recited in claim 1 or 3 and the recombinant protein species recited in claims 12-18 are listed below, which do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the various sequence species do not share significant structural elements:

Nucleic acid molecule species (claims 1 and 3): SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 8, SEQ ID NO: 10, the nucleotide sequence recited in claim 1(c), SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 45, SEQ ID NO: 46, SEQ ID NO: 47, SEQ ID NO: 48, the nucleotide sequence recited in claim 3(g), and the nucleotide sequence recited in claim 3(h).

Recombinant protein species: protein encoded by SEQ ID NO: 5; protein encoded by SEQ ID NO: 6; protein encoded by SEQ ID NO: 8; protein encoded by SEQ ID NO: 10; protein encoded by the nucleotide sequence recited in claim 1(c); protein encoded by SEQ ID NO: 12; protein encoded by SEQ ID NO: 13; protein encoded by SEQ ID NO: 45; protein encoded by SEQ ID NO: 46; protein encoded by SEQ ID NO: 47; protein encoded by SEQ ID NO: 48; protein encoded by the nucleotide sequence recited in claim 3(g); and protein encoded by the nucleotide sequence recited in claim 3(h).

5) Applicants are required, in reply to this action, to elect a single disclosed species even though this requirement is traversed.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record, showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C § 103(a) of the other invention.

6) The Office has established lack of unity between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

7) In the event of rejoinder, the lack of unity requirement between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper lack of unity requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See 'Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)', 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.* Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply wherein the lack of unity requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

8) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of after-final amendments is (571) 273-8300.

9) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

December, 2005

S. DEVI, PH.D.
PRIMARY EXAMINER

Abstract American Society for Microbiology, Chicago, Illinois, Vol. 99, page 89, 30 May - 03 June, 1999

XP-000971104

P.D. 30.05.1999
P. 1

B/D-306. Control Mechanism of the 200 kD Protein Gene Expression in *Moraxella (Branhamella) catarrhalis*

K. SASAKI, L. MYERS, S.M. LOOSMORE, M.H. KLEIN, Pasteur Merieux Connaught Canada, North York, Ontario, CANADA

Previously, we cloned and sequenced a gene encoding a high molecular weight (200 kD) adhesin protein from a strain of *Moraxella catarrhalis*. SDS-PAGE and Western blot analyses showed that not all strains of *M. catarrhalis* produced the 200 kD protein. However, PCR amplification of the entire 200 kD protein gene clearly showed that all strains, including those which do not produce this protein, possessed the entire gene. The result suggests that there may be a phenotypic switch for the expression of 200 kD protein gene. When we PCR-amplified and sequenced a 700 bp DNA fragment including the 5' region of 200 kD protein gene from different strains, we found a G-tract in the 5' region. For the normal level of expression of 200 kD protein gene, the number of Gs in the G-tract had to be a multiple of 3 (3, 6 or 9), in general. Moreover, when we PCR-amplified and sequenced the entire 200 kD protein gene from a spontaneous mutant, which had lost the ability to produce 200 kD protein, and compared the gene sequence with that from its parent strain, the only difference between the two was the number of Gs in the G-tract. The parent strain had nine Gs in the G-tract, but the mutant had only eight Gs. Thus, the number of Gs in the G-tract is the phenotypic switch for controlling the expression of 200 kD protein gene in *M. catarrhalis*.